REMARKS

The applicants would like to thank the Examiner for the careful attention given the application in the previous Final Office Action mailed April 20, 2009. Presently, claims 1-12, 14-27, 29-39, 41-42, 54-65, 67-81, 83-94, 96-98 and 112-125 are pending in the application and stand rejected. All rejections are respectfully traversed in their entirety, including all reasons and rationale for the rejections.

Applicants have amended the claims as indicated above and are also resubmitting the IDS originally filed September 19, 2008, as referenced in paragraph 1. of the previous Office Action. The amendments to the claims are fully supported by the specification as filed, no new matter has been added. The claim amendments and new claims herein are introduced solely to expedite prosecution without prejudice or disclaimer of any previously claimed subject matter. Applicant has not dedicated or abandoned any unclaimed subject matter and has not acquiesced to any rejections or objections made by the Office by introducing the amendments and new claims herein. Applicant expressly reserves the right to pursue prosecution of any presently excluded or cancelled subject matter or embodiments in one or more future continuing patent applications.

35 USC section 112

Claim 125 stands rejected for lack of antecedent basis regarding the phrase "the individual's lifetime". Appropriate correction has been made.

35 USC section 103

Claims 1-3, 5-7, 9-10, 14, 15, 16-18, 20-22, 24-25, 29, 30-37, 41, 42, 54, 56, 58-60, 62-63, 67-70, 72, 74-76, 78-79, 83-86, 88-92, 96-98, 112-119 and 124-125 stand rejected under 35 USC section 103(a) as being unpatentable over "Simulation of in vivo loading conditions of nitinol vascular stent structures" by F.D. Whitcher (Whitcher) in view of U.S. Patent No. 5,594,651 to St. Ville (St. Ville). The rejection is respectfully traversed.

Whitcher appears to discuss the use of AutoCAD to design a geometric model of a 1/8 sub-section of the Symphony stent which has been developed by analysts using various approximations including in-plane representation and equating a weld joint with a rigid contact surface. Force loads which are approximated as a vector component of a pressure load on the sub-section acting only in effective radial direction.

Whitcher does not teach or suggest a stress/strain/deformation analyzer that receives a finite element model or mesh representing a geometric model of an anatomical feature and a medical device. At best, Whitcher discusses discretization of a sub-section of a stent only using a variety of approximations as discussed above. There does not appear to be any disclosure in Whitcher regarding a finite element model or mesh of an anatomical feature or of a geometry generator that generates such a model.

Although pulsatile forces and pressure differentials in arteries are considered in Whitcher as well as the effect of various physiological variations on these parameters, there is no teaching or suggestion of a stress/strain/deformation analyzer that simulates an interaction between an anatomical feature and a medical device over at least one dynamic expansion and contraction cycle. Whitcher does not discuss simulation over an expansion and contraction cycle.

St. Ville discusses a method of manufacturing an object that appears to include designing a geometric model of an object and discretizing the model with field values and potential values are specified at the nodes. A material property matrix is then calculated based on the relationship between values above as a function of a material property coefficients for each finite element. The material property coefficients are then extracted for each finite element and these values compared with material property coefficients of known materials. Manufacturing parameters corresponding to the matched material property coefficients are then determined and the object manufactured in accordance with the parameters.

As opposed to the method of St. Ville that extracts material property coefficients from a simulation that includes known forces and potentials, the system of claim 1

determines predicted stresses, strains and deformations of a medical device due to the interaction of the medical device with an anatomical feature. For the system of claim 1, the material property coefficients are already known. In this regard, St. Ville teaches away from the system of claim 1.

St. Ville discusses a geometry generator, but does not teach or suggest a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature of at least one vascular system. Nor does Whitcher as discussed above. As such, St. Ville also fails to teach or suggest a mesh generator that receives a geometric model of an anatomical feature of at least one vascular system and a medical device. Whitcher also fails to teach or suggest such a mesh generator.

The previous Office Action mentions that it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to combine Whitcher and St. Ville to arrive at the claimed invention. However, Applicants respectfully suggest that because the method of St. Ville involves a simulation that is used to extract material property coefficients where fields and potentials are known and Whitcher's simulation requires the material property coefficients of the subject device as discussed on page 1008, that the combination would likely result in an inoperable device, thus teaching away from the combination.

The disclosure of the cited references teaches away from making the combination. Even if combined, the cited combination fails to teach or suggest all element of claim 1. As such, claim 1 is allowable over the cited art and Applicants respectfully request withdrawal of the rejection. Claim 3 depends from claim 1 and is allowable over the cited references for at least the reasons discussed above with regard to claim 1. Claims 16, 31, 54, 70 and 86 include at least some limitations which are similar to or the same as those of claim 1. These claims are also allowable over the cited references for at least the applicable reasons discussed above. Claims 18, 56 and 72 include limitations which are similar to or the same as claim 3 and are allowable over the references for at least the reasons discussed above with regard to claim 3.

Claims 2, 17, and 32, depend from claims 1, 16 and 31 respectively, and are allowable for at least the reasons discussed above with regard to these claims. Regarding claims 5 and 7, claims 20 and 22, claims 33 and 35, claims 58 and 60, claims 74 and 76 and claims 88 and 90, these claims depend from claims 1, 16, 31, 54, 70 and 86 respectively and are allowable over the cited references for at least the reasons discussed above with regard to these claims.

Regarding claims 6, 21, 34, 59, 75 and 89, neither Witcher or St. Ville teach or suggest an endovascular prosthesis in the form of a stent graft. As such, claims 6, 21, 34, 59, 75 and 89 are allowable over the references for this reason as well as the reasons discussed above with regard to claims 1, 16, 31, 54, 70 and 86 from which these claims depend from respectively.

Claims 9, 24, 36, 62, 78 and 91 depend from claims 1, 16, 31, 54, 70 and 86 respectively and are allowable over the cited references for at least the reasons discussed above with regard to these claims. Claims 10, 25, 37, 63, 79 and 92 depend from claims 1, 16, 31, 54, 70 and 86 respectively and are allowable over the cited references for at least the reasons discussed above with regard to these claims. Claims 67, 83, 96, 112, 114, and 116 depend from claims 54, 70, 86, 1, 16, and 31 respectively and are allowable over the cited references for at least the same reasons discussed above with regard to these claims.

Regarding claims 14, 29, 41, 68, 84 and 97, these claims depend from claims 1, 16, 31, 54, 70 and 86 respectively and are allowable over the cited references for at least the reasons discussed above with regard to these claims. Claims 15, 30, 42, 69, 85, and 98 depend from claims 1, 16, 31, 54, 70 and 86 respectively and are allowable over the cited references for at least the reasons discussed above with regard to these claims. In addition, Whitcher discloses at page 1008 that FE model output was often manipulated and displayed utilizing the Perl data extraction and manipulation language and the "gnuplot" data graphics system (Free Software Foundation, Cambridge, MA) and that these tools allowed rapid evaluation of the large FE data sets. However, Whitcher does not appear to disclose a visualization tool that includes interactive software for visualizing finite element analysis results of three-dimensional grids as

recited in rejected claims 15, 30, 42, 69, 85, and 98. Applicants respectfully request clarification as to whether the Examiner is taking official notice of such teaching, asserting inherency of such teaching or the like so that Applicants may respond with more specificity.

Claims 113, 115, 117, 118 and 119 depend from claims 1, 16, 31, 54 and 86 respectively and are allowable over the cited references for at least the reasons discussed above with regard to these claims. Regarding claim 124, as discussed above, Whitcher fails to teach simulation over at least one dynamic expansion and contraction cycle and claim 124 is allowable for at least this reason as well as the reasons discussed above with regard to claim 70 from which claim 124 depends. Furthermore, the previous Office Action maintains that a "Goodman fatigue analysis" is well known to those of ordinary skill in the art for predicting long term structural integrity by recreating a plurality of dynamic expansion and contraction cycles ("alternating stress"). If official notice is being made as to this assertion, this should be so stated with the provision of documentary evidence. Official notice unsupported by documentary evidence should only be taken by the Examiner when the facts asserted to be well known or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well known. See MPEP 2144.03. Applicants assert that without supporting documentary evidence, the assertion regarding Goodman fatigue analysis is improper and Applicants respectfully request clarification. Claim 125 depends from claim 124 and is allowable for at least the reasons discussed above with regard to claim 124. In addition, Whitcher does not teach or suggest simulation of an amount of dynamic expansion and contraction cycles that would meet or exceed the amount of cycles that would be expected in a lifetime of a particular patient as recited in claim 125. Therefore claim 125 is allowable over the cited references for this reason as well.

Claims 4, 19, 57, and 73 stand rejected under 35 USC section 103(a) as being unpatentable over Whitcher in view of St. Ville and further in view of U.S. Patent No. 5,880,976 to DiGioia III et al. (DiGioia). Applicants respectfully traverse the rejection.

Claims 4, 19, 57 and 73 depend from claims 1, 16, 54 and 70, respectively, and are allowable over Whitcher and St. Ville for at least the reasons discussed above with regard to these claims. In addition, claim 4 recites a geometry generator that receives three-dimensional volumetric data acquired via MRI of at least one anatomical feature(s) of at least one vascular system and generates a geometric model of said anatomical feature(s). As discussed above, Whitcher does not teach or suggest a geometry generator for generation of a geometric model of an anatomical feature. Also, neither St. Ville nor DiGioia teach or suggest such a geometry generator. As such, DiGioia fails to provide the information lacking in Whitcher and St. Ville and claim 4 is allowable over this cited combination of references as well. Although it appears that DiGioia discusses the use of tomographic data obtained from MRI for producing a model of a bone joint, there is no teaching of acquiring three-dimensional volumetric data of an anatomical feature of a vascular system. Claim 4 is therefore allowable over the cited combination. Claims 19, 57 and 73 include the same or similar limitation to that of claim 4 and are also allowable over the cited combination of references for at least the same reason.

Claims 8, 23, 61 and 77 stand rejected under 35 USC section 103(a) as being unpatentable over Whitcher in view of St. Ville and further in view of "Automated Mesh Generation of an Arterial Bifurcation Based upon In Vivo MR Images" by Seung Lee et al. (Lee). Applicants respectfully traverse the rejection.

Claims 8, 23, 61 and 77 depend from claims 1, 16, 54 and 70, respectively, and are allowable over Whitcher and St. Ville for at least the reasons discussed above with regard to these claims. Lee fails to cure the deficiencies of Whitcher and St. Ville and the claims are allowable over this cited combination as well. In addition, Lee does not appear to teach a software application which generates surface points from three dimensional volumetric data which are then converted into stereolithography, slice files, IGES files or a combination thereof as recited in claims 8, 23, 61 and 77. The claims are allowable over the cited combination for this reason also.

Claims 11-12, 26-27, 38-39, 64-65, 80-81 and 93-94 stand rejected under 35 USC section 103(a) as being unpatentable over Whitcher in view of St. Ville and further

in view of "Computational Mechanics Moves Ahead" by Peter J. Raboin (Raboin). As discussed above, the combination of Whitcher and St. Ville fails to teach all elements of claims 1, 16, 31, 54, 70 and 86 from which claims 11-12, 26-27, 38-39, 64-65, 80-81 and 93-94 depend, respectively. Raboin does not teach or suggest simulating an interaction between anatomical feature(s) and a medical device over at least one dynamic expansion and contraction cycle of the vascular system to determine the predicted stresses, strains, and deformations of said candidate medical device design by said load data. As such, Raboin fails to cure the deficiencies of Rogers and St. Ville and claims 11-12, 26-27, 38-39, 64-65, 80-81 and 93-94 are allowable over the cited references.

Claims 55, 71, 87, and 120-123 stand rejected under 35 USC section 103(a) as being unpatentable over Whitcher in view of St. Ville and further in view of "Failure of All-ceramic Fixed Partial Dentures in vitro and in vivo: Analysis and Modeling" by J.R. Kelly, J.A. Tesk, and J.A. Sorensen (Sorensen). As discussed above, the combination of Whitcher and St. Ville fails to teach all elements of claims 54, 70 and 86 from which claims 55, 71, 87, and 120-123 depend, respectively. Sorensen fails to provide the information absent from Whitcher and St. Ville, thus the claims are also allowable over this cited combination as well.

In addition, regarding claims 120-123, it is not clear that Sorensen discloses simulating stresses/strains/deformations to a point of failure. Although Weibull failure probability calculations, incorporating FEA stress profiles are discussed, simulation to a point of failure is not. In addition, the identification of the location of maximum principle tensile stresses and the correlation of such locations with fractographic observations does not require simulation to a point of failure. Furthermore, claim 122 is directed to the method of claim 120 further including varying one or more in vitro failure mode test parameters based on an additional step of comparing simulation data generated by said step of simulating stresses, strains, and deformations imposed on said candidate medical device design by said load data representing said anatomical feature and additional simulation data generated by said step of simulating stresses, strains, and deformations imposed on said candidate medical device design by said load data in said

in vitro failure mode test. Claim 123 includes the limitations of claim 122 and recites that the one or more in vitro failure mode test parameters include test frequency. These limitations are not taught or suggested by Sorensen, Whitcher or St. Ville, and the claims are allowable over the cited references for at least these reasons as well.

CONCLUSIONS

In view of the foregoing amendments and remarks, Applicants respectfully submit that the Office can properly withdraw the outstanding claim rejections and that the pending claims herein are in condition for allowance. Applicants therefore respectfully request that the Office withdraw the outstanding claim rejections and issue a notice of allowance.

In the unlikely event a fee calculation document or other pertinent document is separated from this submission and the Office determines that an extension and/or other relief is required, Applicant petitions for any required relief, including extensions of time, and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. **50-2949**.

Respectfully submitted,

/William B. Anderson/

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William B. Anderson
Registration No. 41,585
Customer No. 82764

GRANT ANDERSON LLP
6540 LUSK BOULEVARD, SUITE C210
SAN DIEGO, CA 92121
TELEPHONE (858) 623-3227
FACSIMILE (858) 623-3224